

# **METHOD FOR MODERATION OF BACK PAIN**

## **FIELD OF THE INVENTION**

This invention relates to a method for moderation of back pain.

## **BACKGROUND OF THE INVENTION**

Lower back pain is usually treated with pain killing/alleviating or muscle relaxation drugs. Physical treatments also include massage or heating pads directly applied onto the proximity of the lower back where pain is occurring. Acupuncture or acupressure is also commonly used to alleviate pain associated the lower or upper back. For example, acupuncturists have been applying needles at UB23 AND UB25 acupuncture points on both sides of the lower back to effect pain alleviation. TENS, Transcutaneous Electro-Neural Stimulation, has also been used by patients, directly on the area of pain, to temporarily alleviate pain. However, there has been no effective way of long term curing or moderating lower or upper back pain once it occurs.

Wei-Cheng Wang, Head Acupuncture Instrument (HAI), U.S. Patent No.:6280454B1,2001, describes a head acupuncture device using multiple electrodes integrating magnets and stimulating signal proportional to a rhythm. For applying physiological stimulations to acupuncture points on the head, electrical pulse of 50-110 volts with frequency between 0.3 – 3.4 KHz has been used.

Recently, in trying to use HAI for the treatment of various disorders such as insomnia, stress , headache, etc., we discovered that, a companion physiological stimulation on each group of acupuncture points surrounding K1 and FHA ( foot heel area, a newly found singular vital point ) on the bottom of each foot, with or without HAI, has a remarkable effect on reducing the lower and upper back pain.

## SUMMARY OF THE INVENTION

The primary objective of this invention is to treat lower or upper back pain by physiological stimulation of each group of acupuncture points surrounding K1 and FHA ( foot heel area, a newly found singular vital point ) vital points on the bottom of each foot. The method described below further employs a pair of shoe-like physiological stimulation devices (abbreviated as PSD-shoe) to effect such physiological stimulations. A patient desiring to moderate his or her back pain places an insole carrying a pair of electrodes on the bottom of each foot, and applying electrical, heat and magnetic stimulation to the group of acupuncture points surrounding K1 and FHA acupuncture points, through these electrodes and sensors. This has the effect of moderating back pain in the patient. The electrodes and sensors, pulse generating circuitry, and power supply are both all contained and conveniently packaged in a shoe-like housing, or with the pulse generating and control circuit in a separate unit connected to the electrodes and sensors inside the shoe-like device. A user will wear this shoe-like device just like wearing a regular pair of shoes, with the electrodes and sensors in contact with each foot through adhesive or other means to ensure close contact during the treatment.

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view showing an insole, a preferred embodiment of the stimulating device being received in a shoe;

Fig. 1A is a perspective view showing K1 and FHA acupuncture points, a preferred embodiment of acupuncture points in relation to the foot print.

1           Fig. 2 is an exploded perspective view of the stimulating device and an  
2   embodiment of the fixing element in the shoe in Fig. 1;

3           Fig. 3 is a schematic view in partial section showing the relative positions  
4   between the stimulating device and the fixing element;

5           Fig. 4 is a block diagram of the control circuit of the present invention;

6           Figs. 5A and 5B are schematic views showing the output wave patterns after  
7   being converted from low frequency signal;

#### 8   DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

9           The preferred embodiment of insole was shown in Fig. 1. Figure 1A was showing  
10   the placement of electrodes relating to a foot print and two acupuncture points. Figure 1  
11   was showing the stimulating device, namely, the insole with electrodes with relation to  
12   the fixation device. With reference to Figure 1A, two electrodes were placed accordingly  
13   to K1 acupuncture point and FHA areas. With reference to Figure 1, the stimulating  
14   device in accordance with the present invention includes a fixing element (10), at least  
15   one pair of electrical plates (11,12), a heat element (13), at least one magnetic stone  
16   (14,15) and a control circuit (not shown).

17           With reference to Fig. 2 again that the fixing element (10) in this embodiment  
18   includes a pad (101) and an insole (102) securely connected to the pad (10). The pad (10)  
19   has holes (103) corresponding to the magnetic units (14,15) such that the magnetic units  
20   (14,15) are able to be received in the holes (103). The resistance (13) is substantially  
21   located along a contour of the insole (102). The electrical plates (11,12) respectively are

1 then securely applied on top of the magnetic units (14,15). Bolts (not numbered) are used  
2 to firmly engage the pad (10) to the insole (102). It is to be noted that the electrical plates  
3 (11,12) may have one positive plate and one negative plate. Other embodiments show that  
4 the combination of the electrical plates (11,12) may have one positive plate and the others  
5 are negative plates or vice versa.

6 With reference to Fig. 3, after the assembly of the stimulating device of the  
7 present invention, the electrical plates (11,12) (only the electrical plate (11) is shown)  
8 correspond to the magnetic units (14,15) (only the energy stone (14) is shown).

9 With reference to Fig. 4, the control circuit of the present invention includes a  
10 signal generating unit (20), a power amplifying/boosting circuit (30), a temperature  
11 control circuit (40) and a power source (50).

12 The signal generating unit (20) generates a mediate or a low frequency signal and  
13 sends the generated signal to the electrical plates (11,12) so as to stimulate the muscle and  
14 vital points around the electrical plates (11,12). The signal generating unit (20) includes a  
15 mediate frequency oscillator (21), a low frequency conversion circuit (22) and a  
16 magnitude control circuit (23). The mediate frequency oscillator (21) is to generate a  
17 mediate frequency signal which is then converted to a low frequency signal by the low  
18 frequency conversion circuit (22). The magnitude control circuit (23) aims to control the  
19 strength of the converted low frequency signal.

20 With reference to Figs. 5A and 5B, the drawings show two different kinds of  
21 working waves for the magnitude control circuit (23) by the low frequency conversion  
22 unit (22).

1           The power amplifying/boosting circuit (30) connecting to the output of the signal  
2     generating unit (20) includes a power amplifying circuit (31) and a voltage booster (32).  
3     The signal sent by the signal generating unit (20) is processed respectively by the power  
4     amplifying circuit (31) and the voltage booster (32) and sent to the electrical plates  
5     (11,12).

6           The temperature control circuit (40) includes an output connecting to the  
7     resistance (13) for controlling the temperature of the fixing element (10).

8           The power source (50) is composed of a filter (51) and a transformer (52). The  
9     transformer (52) provides electricity to the resistance (13) via the temperature control  
10    circuit (40) and rectifies the current from the filter (51).

11          Therefore, from the foregoing description, the preferred embodiment of the  
12    present invention shows that the fixing element (10) is composed of a pad (shoe pad) and  
13    an insole (102) such that the user is able to place the fixing element (10) inside the shoe  
14    with the heat element (13) substantially surrounding the contour of the insole (102) and  
15    the electrical plates (11,12) and the magnetic units (14,15) received in the pad (101). With  
16    the foregoing arrangement, the user is able to simultaneously stimulate and provide mild  
17    thermal effect to the vital points surrounding K1 and FHA.

18          Therefore, with the temperature provided by the resistance (13), the specific  
19    portion of the patient's body is treated for swelling and the like. Also the electrical plates  
20    (11,12) provide a massaging effect to the vital points and surrounding muscles with the  
21    assistance of the power amplifying circuit (31) and the voltage booster (32). The effect by  
22    the resistance (13) is much the same as the "warm-up" before starting a sport, which is

1 able to increase the blood circulation, the flexibility of the body and metabolism of the  
2 body.

3 It is to be understood, however, that even though numerous characteristics and  
4 advantages of the present invention have been set forth in the foregoing description,  
5 together with details of the structure and function of the invention, the disclosure is  
6 illustrative only, and changes may be made in detail, especially in matters of shape, size,  
7 and arrangement of parts within the principles of the invention to the full extent indicated  
8 by the broad general meaning of the terms in which the appended claims are expressed.

9 Our discovery derives from speculation regarding the potential biological effects  
10 of electrical stimulation of the group of acupuncture points surrounding K1 and FHA  
11 acupuncture points.

12 Volunteer patients were tested for lower back pain. All subjects use a pair of the  
13 PSD-shoe devices on each of their feet for approximately thirty minutes for each  
14 treatment session. Different sizes of the PSD-shoe were used for each tested subject to  
15 ensure that the two sets of electrode and heating pads on each insole are placed directly on  
16 the group of acupuncture points surrounding K1 and FHA acupuncture points. After  
17 treatment, the pain level of each tested subject was recorded. In order to clinically validate  
18 the trials, methods used to record the pain level are conformed to clinically acceptable  
19 ones including Numerical Scale, Face Rating Scale, Medical Outcomes Study Short Form  
20 36 (SF-36) and Roland and Morris Disability Scale. The total treatment consists of three  
21 treatment sessions each week for four weeks. After four weeks, a statistically significant  
22 reduction in lower back pain was observed in each test group. In most of cases, lower

1 back pain was reduced significantly. To ensure that the pain reduction was not temporary,  
2 each patient was required to report to the physician once every week, after the treatment  
3 session was completed, the status of his/her back pain. The majority of the tested subjects  
4 continued to report either no recurring of the back pain or a sustained improvement of  
5 back conditions over what it was before the treatment.

6 The areas of the electrodes used in these applications tend to be rather large in  
7 order to provide a broad range of stimulation to a group of muscle or nerves. The  
8 mechanism of action is not thoroughly understood. However, it is expected that the back  
9 pain conditions should be moderated due to the combination effects of remote peripheral  
10 nerve and muscular stimulation that will be enhancing cellular permeability and  
11 improving intercellular fluid circulation. The technique accomplished by the device is  
12 referred to as electro-acupuncture or non-invasive nerve stimulation, and has components  
13 of acupuncture effect and acupressure. While it is used the shoe-like non-invasive nerve  
14 stimulation device, any suitable means of applying electrical or physiological stimulation  
15 to the group of acupuncture points surrounding K1 and FHA acupuncture points should  
16 work to moderate lower back pain.

17 In order to have a better understanding of the method of the present invention, the  
18 following paragraph lists the steps used in the method which includes non-invasively and  
19 concurrently stimulating the group of stimulation points surrounding K1 and FHA  
20 acupuncture points. The non-invasively stimulating step comprises at least a set of non-  
21 invasive electrical stimulation.

22 The method includes the steps of mounting a non-invasive stimulation device

1 onto the group of stimulation points surrounding K1 and FHA acupuncture points; and  
2 stimulating the group of stimulation points surrounding K1 and FHA acupuncture points,  
3 wherein the stimulating comprises at least a pair of electrical stimulation. Furthermore,  
4 the method includes mounting at least two electrodes with each electrode onto each group  
5 of stimulation points surrounding K1 and FHA acupuncture points, generating a  
6 stimulation signal and delivering the stimulation signal to the each at least one pair of  
7 electrode to stimulate the group of stimulation points surrounding K1 and FHA  
8 acupuncture points.

9         Still, the method of moderating lower back pain in a patient with abnormal lower  
10 back pain, the method includes mounting a non-invasive stimulation device onto the  
11 group of stimulation points surrounding K1 and FHA acupuncture points, generating a  
12 stimulation signal, and stimulating the group of stimulation points surrounding K1 and  
13 FHA acupuncture points, wherein the mounting step comprises providing a multiple  
14 electrode carrying insole, housed in a shoe-like device, carrying the at least two electrodes  
15 and a circuit for generating the stimulation signal and providing securing means for  
16 mounting the at least two electrodes on the said insole near the group of stimulation  
17 points surrounding K1 and FHA acupuncture points, wherein said delivering step  
18 comprises delivering an intermittent stimulation signal, wherein said delivering step  
19 comprises delivering a continuous stimulation signal.

20         While the preferred embodiments of the methods have been described in  
21 reference to the environment in which they were developed, they are merely illustrative of  
22 the principles of the inventions. Other embodiments and configurations may be devised

1 without departing from the spirit of the inventions and the scope of the appended claims.